

### **REMARKS**

Reconsideration of this application is requested. Claims 1-8, 11-25 and 62-66 are in the case.

#### **I. DRAWING**

In response to the suggestion that the subject matter of this application admits of illustration, a proposed drawing was attached to the response filed July 31, 2000. A further copy is attached. The specification has been amended to include a brief description of this drawing. A formal drawing will be submitted once the application is in condition for allowance and the Examiner has approved the proposed drawing. No new matter is entered.

#### **II. THE 35 U.S.C. 112, SECOND PARAGRAPH, REJECTION**

Claims 1-8, 11-25 and 62-66 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite because claim 1 refers to a fibrous polymeric material and a recrystallized polymeric material consisting of the same polymer with a different melting point. This rejection is respectfully traversed.

A polymeric material, even if of a single polymer, will have a melting point range. In the present invention, the first 5 to 50% of the polymer to melt over this range makes up the recrystallised melt phase. In order to clarify claim 1, the

expression "the fibers and melt phase being of the same polymer and being derived from common molecularly oriented precursor polymeric fibers by melting an proportion of the polymer of the precursor fibers" has been inserted. The term "selective melting" objected to by the Examiner in the Advisory Action is no longer employed in the claims. The expression "molecularly oriented" does have clear basis in the specification as filed at page 2, lines 12-15 where the benefits of molecular orientation in fibers are discussed. It is clear from this passage that an element of molecular orientation is established and maintained in the product, which is the reason why not all of the fiber is melted. It is believed the proposed new claim language does not give rise to new issues requiring further consideration and/or searching, and no new matter is entered. Entry of the claims as presently proposed to be amended is, accordingly, respectfully requested.

Withdrawal of the outstanding 35 U.S.C. 112, second paragraph, rejection is believed to be in order. Such action is respectfully requested.

### **III. DOUBLE PATENTING**

Claims 1-8, 11-25 and 62-66 stand rejected on alleged obviousness-type double patenting grounds over U.S. patent 6,017,834 in view of U.S. patent 5,017,627. That rejection is respectfully traversed.

Claim 1 has been amended to recite that the fibers are of maximum dimension 1 mm. This is a consequence of the preferred powderizing technique (see page 4, lines 23-25). Such a material is an undisclosed patentable selection over the disclosure of Ward et al and is not obvious over Bonfield et al. Basis for a 1 mm upper limit is present on page 4, line 23 to 24 where powderizing gives a maximum dimension of up to 1 mm.

Withdrawal of the outstanding obviousness-type double patenting rejection is believed to be in order. Such action is respectfully requested.

#### **IV. THE OBVIOUSNESS REJECTIONS**

Claims 1-8, 11-25 and 62-66 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Ward et al (U.S. patent 6,017,834) in view of Bonfield et al (U.S. Patent 5,017,627). That rejection is respectfully traversed.

Neither Ward nor Bonfield discloses that the polymer should include fibers of maximum dimension 1 mm, such as it can be extruded by hydrostatic extrusion as can the present material. Ward et al only disclose that the diameter of the fiber may be in the range of 0.005 to 0.05mm, whilst the length is exemplified as process to at least 3mm (see sheet dimension). Example 6 of Ward refers to chopped SNIA fibers, but such materials are not taught at lengths

as short as 1mm. The starting material chopped fiber of the present case is supplied at 3.2-3.8mm (Table 1, page 13).

Even if a person of ordinary skill had contemplated combining the disclosures of Ward and Bonfield, the resulting composite would not have had the same properties as the now claimed material. The present materials including fiber of defined maximum dimension, as provided by e.g. powderizing, are capable of hydrostatic extrusion while containing significant levels of filler.

Withdrawal of the obviousness rejection based on Ward and Bonfield is believed to be in order. Such action is respectfully requested.

Claims 1-8, 11-25 and 62-66 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Turner et al (U.S. patent 4,662,887) in view of applicants' disclosure. That rejection is respectfully traversed.

Turner et al (Example 2) disclose the use of carbon fibers of less than 1 mm length injection molded with PEEK polymer. Selective melting of polymeric fiber of less than 1 mm maximum dimension is not disclosed. Furthermore, the presently amended claim recites that the fiber and recrystallized melt are derived from a common molecularly oriented precursor polymeric fibers by selective melting. Such is not obvious from Turner.

Turner does not render any of the currently claimed matter obvious. Turner itself discloses information that demonstrates the inadequacy of its teaching with regard to at least some of its embodiments. Column 1, lines 37 to 52 note that materials that have too high a modulus will inhibit bone healing. Examples 3 and 4 of Turner have modulus of 41 and 47GN/m<sup>2</sup>, respectively, above the presently preferred range. In addition, it is reported (Column 7, lines 52-55) that these show non-benign response after 30 weeks in dogs. Turner Example 1 in contrast has a lower modulus (3.8GN/m<sup>2</sup>) than that of the preferred range. No clear disclosure can be derived from these examples. No disclosure of favorable ductility is given. It will be realized that the presently claimed materials allow closer matching of bioactivity, modulus, strength and ductility to that of cortical bone, a property not matched by Turner.

Withdrawal of the obviousness rejection based on Turner is believed to be in order. Such action is respectfully requested.

Claims 7-8 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Turner et al (U.S. patent 4,662,887) in view of Dorman et al (U.S. patent 4,842,604). That rejection is respectfully traversed.

Turner discloses use of polymer with fibrous or particulate inorganic reinforcement, whereas the present application relates to the use of a polymeric material that includes its own reinforcement. Thus, the presently claimed

material allows use of a filler which is not itself a reinforcement, but which is preferably a bioactive biocompatible filler such as hydroxyapatite. The knowledge that Turner needs the inorganic material to be a reinforcement would rule out use of the fillers taught in the present invention, i.e. talc, mica, graphite, metal oxides, hydroxides, carbonates and phosphates to those skilled in the art. Turner exemplifies exclusively carbon fibers, a strong reinforcement material.

Dorman clearly does not render replacement of the essential 'inorganic reinforcement' of Turner by non-reinforcing materials such as hydroxyapatite obvious. Turner and Dorman in particular fail to suggest the production of the most preferred materials of the present claims as these require the determination that the materials can be powderized and/or hydrostatically extruded to increase strength.

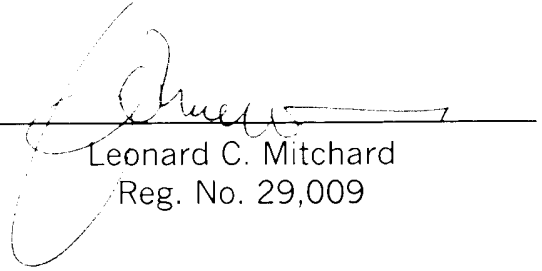
Withdrawal of the obviousness rejection based on Turner and Dorman is believed to be in order. Such action is respectfully requested.

Allowance of the application is awaited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_



Leonard C. Mitchard  
Reg. No. 29,009

LCM:lks  
1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100  
Attachment: Drawing

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS**

1. (Twice amended) A composite material comprising a particulate inorganic filler material and a fibrous polymeric material wherein the fibrous polymeric material comprises molecularly oriented polymeric fibers of maximum dimension 1 mm and a recrystallised melt phase [of the same polymer as the fibers], the fibers and melt phase being of the same polymer and being derived from common molecularly oriented precursor polymeric fibers by melting a proportion of the polymer of the precursor fibers, the recrystallised melt phase consisting of from 5% to 50% by weight of the polymeric material and having a melting point less than that of the molecularly oriented fiber [, the recrystallised melt phase] such as to join[ing] areas of adjacent fibers to form a network or continuous three dimensional matrix which binds the fibers and filler together.

2. (Twice amended) A composite material as claimed in Claim 1, wherein the [the] precursor fiber is [cut to a] of maximum length of 0.5 mm.



FIGURE

